DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-822/S-011
NDA 21-046

Forest Laboratories, Inc.
Attention: Tracey Varner
Manager, Regulatory Affairs
Harborside Financial Center
Plaza Three, Suite 602
Jersey City, NJ 07311

Dear Ms. Varner:

Please refer to your supplemental new drug application dated August 10, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celexa (citalopram hydrobromide) 20 mg and 40 mg Tablets (20-822) and 10 mg/5 ml Oral Solution (21-046).

We additionally refer to an Agency approvable letter dated November 17, 2000, for the above supplemental application.

We acknowledge receipt of your submission dated January 17, 2001, providing for a response to our November 17, 2000, Agency letter.

This "prior approval" supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY-Drug-Drug Interactions**, and the **PRECAUTIONS-Drug Interactions** sections, and the addition of new sections entitled **Ketoconazole**, **Theophylline**, and **Triazolam** under the **PRECAUTIONS-Drug Interactions** section.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as agreed upon in the submitted draft labeling dated January 17, 2001.

Please submit 20 paper copies of the final printed labeling (to each application) ten of which are individually mounted on heavy weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-822/S-011." Approval of these submissions by FDA is not required before the labeling is used.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted January 17, 2001).

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research